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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/816,079      03/13/97      WIRONEN      J      TB-101

GERARD H BENCEN  
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ORLANDO FL 32801

HM22/0202

EXAMINER

BERMAN, A

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

02/02/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

08/816,079

Applicant(s)

WIRONEN ET AL.

Examiner

Alysia Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 November 2000.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

1. Receipt is acknowledged of the request for extension of time and amendment filed November 28, 2000. Claims 38 and 39 have been added. Claims 1-39 are pending. Claims 1, 8, 9, 12, 29, 33 and 34 have been amended.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "organic osteogenic component" broadens the scope of the claims beyond the scope of the disclosure.

4. Claims 1-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for demineralized bone matrix, bioactive glass ceramic,  $\text{SiO}_2\text{-Na}_2\text{O-CaO-P}_2\text{O}_5$ , bioactive ceramic, calcium phosphate ceramic, hydroxyapatite, hydroxyapatite carbonate, corraline hydroxyapatite, calcined bone, tricalcium phosphate, bone morphogenetic protein, TGF- $\beta$  and PDGF, does not reasonably provide enablement for substantially bioabsorbable, organic osteogenic

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components. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. One skilled in the art would not be enabled to determine what organic components other than those instantly disclosed would be appropriate as a bioabsorbable osteogenic component for use in the instant invention without undue experimentation.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

6. Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1-39 are indefinite because the independent claims recite "a sufficient period of time to induce bone formation at said site", which renders the claims indefinite. The time period sufficient to induce bone formation is not further defined in the claims or the specification. Therefore, the metes and bounds of the claims cannot be determined.

8. Claims 7-9 recite the limitation "demineralized bone matrix" or "DBM". There is insufficient antecedent basis for this limitation in the claim.

9. Claim 11 recites the limitation "component (ii)" in line 1. There is insufficient antecedent basis for this limitation in the claim.

10. Claims 28 and 36 are indefinite because they recite "U-shapes." This rejection is maintained for reasons of record.

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11. Claims 38 and 39 are indefinite because they contain abbreviations. It unclear what Applicants intend by the abbreviations "DBM" and "BMP". It is suggested that the names of any components be fully written out at the first instance in the claims followed by any abbreviations in parentheses for use in further claims.

12. This application is replete with 35 U.S.C. 112 issues. The above are just some examples. Applicant is required to review all of the claims for 35 U.S.C. 112 issues and make appropriate corrections.

### ***Response to Arguments***

13. Applicant's arguments filed November 28, 2000 have been fully considered but they are not persuasive.

14. Applicant argues that "U-shapes" would be readily understood by one skilled in the art. This is a relative term. Neither the claims nor the specification supply any further exclusive definition of what is meant by this term. Therefore, the metes and bounds of the claims cannot be determined.

### ***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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16. Claims 1-4 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Ninomiya. This rejection is maintained for reasons of record.

17. Claims 1-6, 10-12, 21, 24, 27-30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,191,747 ('747). This rejection is maintained for reasons of record.

***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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20. Claims 1-6, 10-12, 21, 24, 27-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,191,747 ('747). This rejection is maintained for reasons of record.

21. Claims 7, 8, 13-20, 22, 23 and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,191,747 ('747) as applied to claims 1-6, 10-12, 21, 24, 27-30 and 32 above, and further in view of US 5,422,340 ('340). This rejection is maintained for reasons of record.

22. Claims 13, 14, 22, 23, 25, 26 and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,191,747 ('747) as applied to claims 1-6, 10-12, 21, 24, 27-30 and 32 above, and further in view of US 5,484,601 ('601). This rejection is maintained for reasons of record.

### ***Double Patenting***

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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24. Claims 1-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 09/014519. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons stated in paper no. 15.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

25. Applicant's arguments filed November 28, 2000 have been fully considered but they are not persuasive.

26. Applicant argues that Ninomiya teaches deactivation or removal of all osteogenic components. Merriam-Webster's Collegiate Dictionary, 10<sup>th</sup> Ed., page 823, defines "osteogenic" as "originating in bone". By this definition, the deactivated demineralized bone matrix gelatin of Ninomiya encompasses an organic osteogenic component as instantly claimed.

27. Applicant argues the only teaching of an organic osteogenic component in US '747 is denatured bone meal wherein any protein-based osteogenic components are completely denatured. As stated above, the denatured bone meal of US '747 encompasses the organic osteogenic components as instantly claimed.



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28. Applicant argues that US '747 does not enable the use of gelatin as a carrier.

The intended use of a component in a composition does not render the composition *per se* patentable. *In re Pearson*, 181 USPQ 641 and *In re Tuominen*, 213 USPQ 89.

29. Applicant argues that US '340 teaches away from the use of gelatin as a carrier and, therefore, does not cure the deficiencies of US '747. All disclosures in a reference patent must be evaluated, including non-preferred embodiments. A reference is not limited to disclosure of the specific working examples. See *In re Mills* 176 USPQ 196 (CCPA 1972). Disclosure of a composition of matter in a reference may be anticipatory even though the reference indicates that the composition is not preferred or even that it is unsatisfactory for the intended purpose. See *In re Nehrenberg* 126 USPQ 383 (CCPA 1960). The reference teaches an implantable composition comprising gelatin.

30. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine US '340 with US '747 is to obtain an implantable composition that induces bone formation.

31. Applicant argues that US '601 teaches a flowable composition with a liquid carrier, which is contrary to Applicants' invention. Dr. Wironen's Declaration filed

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January 26, 2001 has been considered. US '601 teaches that by "flowable" is meant a composition that is "shape-sustaining but readily deformable" (col. 3, lines 30-33).

Further, as stated above, the intended use of a component in a composition does not render patentability over the prior art composition containing that component even if used for a different purpose. US '601 teaches that the addition of gelatin to the carrier significantly improves the ability of the composition to contain the bone powder.

32. Applicant argues that the instant invention does not teach thermally treated gelatin as claimed in copending Applicant No. 09/014519. At page 11, lines 13-14 of the instant application the gelatin is heated to above 50° C. This constitutes thermal treatment within the scope of copending Applicant No. 09/014519.

33. As to the arguments of extraordinary commercial success, Applicants have not supplied any comparison data to support such an aversion. The Declaration of January 26, 2001 refers to attached Exhibits A-D. No such exhibits were attached to the Declaration. Therefore, the examiner cannot make a judgement as to any extraordinary commercial success.

### ***Conclusion***

34. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


### ***Correspondence***

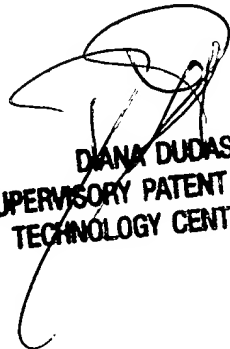
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 or 703-305-4456 for regular communications and 703-308-7922 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.

  
Alysa Berman  
Patent Examiner  
January 24, 2001

  
DIANA DUDASH  
SUPERVISORY PATENT EXAMINER  
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